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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/827,565

04/19/2004

Joseph C. Eder

1001.1750101

3215

28075 7590 11/12/2008
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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/827,565	Applicant(s) EDER, JOSEPH C.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-27, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 28 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/05, 7/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Claims 17-27, 29, 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species II and III, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/27/08.

Claim Objections

2. Claim 28 is objected to because of the following informalities: Claim 28 recites the step of securing the members in an arrangement where the distal end region of the first tubular member extends distally beyond the distal end region of the second tubular member. The examiner would like to bring this to the Applicant's attention because previous claims recite the second tubular member extending beyond the distal end of the first tubular member. The designation of first and second tubular member is arbitrary, but for the sake of continuity Applicant may want to amend the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 8, 9, 13, 14, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Banka (US 4299226). Banka discloses a coronary dilation device comprising an intravascular catheter including a first tubular member 100 and a second tubular member 205, the distal end region of the second tubular member extending about ten or more centimeters distally beyond the

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distal end region of the first tubular member (col. 2, lines 59-61, Col. 3, lines 21-45). The first and second tubular members are parallel and coaxial. See Fig. 3. Banka inherently discloses the steps of providing the first and second tubular members. Banka discloses the step of securing the first and second tubular member together in an arrangement wherein the distal end of the second tubular member extends distally beyond the distal end region of the first tubular member (col. 3, lines 30-35).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5368567) in view of Banka. Lee discloses a dilation catheter comprising an intravascular catheter including a first tubular member 21 and a second tubular member 20, the second tubular member extending beyond the distal end of the first tubular member, and a sheath 16 extending over a portion of the first and second tubular members.

7. Claim 1 differs from Lee in calling for the distal region of the second tubular member to extend at least 10 centimeters beyond the distal end of the first tubular member. While Lee clearly shows that the distal end of the second tubular member 20 extends beyond the distal end of the first tubular member 21, it is silent as to the specific distance. Banka teaches a device having a first and second tubular member, wherein the second tubular member extends at least 10 centimeters beyond the distal end of the first tubular member so that the device can be used to

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clear an obstruction. Both Lee and Banka are disclosed as being intended for the same use.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lee to extend the distal end of the second tubular member 10 centimeters beyond the distal end of the first tubular member as taught by Banka so that the device can treat an occlusion in a vessel.

8. Claim 3 calls for the first and second tubular members to be adhesively bonded. Claim 4 calls for the first and second tubular members to be co-extruded. Claim 5 calls for the first and second tubular members to be thermally bonded. At the time the invention was made, it would have been an obvious matter of design choice to secure the first and second tubular members in any known fashion. Applicant has not disclosed that adhesively bonding, co-extruding, or thermally bonding serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Lee and applicant's invention to perform equally well with any means of bonding the first and second tubular members because the means of bonding them does not affect the performance of the device. Therefore, it would have been prima facie obvious to modify the device of Lee to obtain the invention as specified in claims 3-5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

9. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banka in view of Griffin et al (US 2003/0093059) or Lee in view of Banka in view of Griffin. Claim 10 differs from the teachings above in calling for the first and/or second tubular member to include a support structure layer. Claim 11 calls for the support structure layer to be a braid. Claim 12 calls for the support structure layer to be one or more coils. Griffin teaches an intravascular

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catheter comprising a support layer 36 that may be formed of single coils, multiple coils, or a braid (page 2, paragraph 0017). The reinforcement layer allows the device to be inserted through the vasculature without kinking. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Banka or Lee to include a reinforcement layer formed of coils or a braid as taught by Griffin to allow the device to be inserted through the vasculature.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over banks in view of Belden (US 5409455) or Lee in view of Banka in view of Belden. Claim 15 differs from the teachings above in calling for the first and/or the second tubular member to include a taper. Claim 16 calls for both tubular members to have a tapered region that are disposed in an overlapping arrangement. Belden teaches an intravascular catheter including a first 4 and second tubular member 5, the first tubular member having a tapered region and the second tubular member having a tapered region 13, the first and second tapered regions overlapping. See Fig. 5. This tapered configuration allows the device to be inserted through the vasculature gently without damaging the vessel wall. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Banka or Lee to include overlapping tapered portions as taught by Belden so that the device can be inserted through the vasculature without damaging the vessel wall.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763